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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,145	01/30/2001	Eilaz Babaev	24149.14	1226

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EXAMINER	
SHAW, SHAWNA JEANNINE	
ART UNIT	**PAPER NUMBER**
3737	

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/774,145	BABAEV, EILAZ
	Examiner	Art Unit
	Shawna J. Shaw	3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,9-11 and 19-30* is/are pending in the application.

4a) Of the above claim(s) *30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,9-11 and 19-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/29/2004 has been entered.

Election/Restrictions

2. This application contains claims directed to the following patentably distinct species of the claimed invention: A: the species of figures 1-4, and B: the species of figure 5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none of the claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with George Likourezos on 08/24/2004 a provisional election was made without traverse to prosecute the invention of species A, claims 1-36, 9-11 and 19-29. Affirmation of this election must be made by applicant in replying to this Office action. Claim 30 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-3, 9-11 and 19-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-10, 13-16, 18, 21 and 22 of U.S. Patent No. 6,663,554. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the patent, ultrasound is delivered using standing waves applied at a distance $d=n \times \lambda/2$ (col. 6). Claims 1-3, 9-11 and 19-27 are therefore an obvious broadening and/or variation of the patented claims. Furthermore, it would have been obvious to replace the groove or ring of Patent No. 6,663,554 with a bushing since they both provide the same function of increasing the ultrasound radiation pressure.

Claim Objections

4. Claim 26 is objected to because of the following informalities: In line 3, the therapeutic effect of dissolving blood clots appears to be inconsistent with the method of treating of an external wound. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 6, 9-11 and 19-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not adequately teach how to create and maintain ultrasound standing waves in air that are adequate for providing bactericidal and therapeutic effects. It appears that effective ultrasound waves may only be maintained in the air by use of a propagation medium or spray particles (see Patent No. 6,478,754 to the same inventor, col. 2 line 66 – col. 3 line 2, col. 7 lines 54-58), however the use of such particles for this purpose has not been adequately set forth in the present disclosure. If the applicant has discovered a method or means for creating and maintaining ultrasound standing waves in air without the use of a propagation medium or spray, the examiner respectfully requests an affidavit stating as such to overcome this rejection under 112 first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9-11 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear from the disclosure what *structure* corresponds to the 112 sixth paragraph limitation "means for creating and maintaining the ultrasound standing waves in air by adjusting the non-contact distance between the distal radiation surface and the external wound." It appears that the structure of claim 9 merely contains an ultrasound transducer (8) and tip (12) that is manually moved back and forth toward a wound surface (6) by an operator. See the specification, middle of page 5. (Furthermore, if the wound surface (6) is part of "the

means for creating and maintaining standing waves," the examiner further points out that parts of the body cannot be claimed).

Claim Interpretation

It is understood from the specification that standing waves occur as a result of (constructive) superposition of incident and reflected ultrasound waves, wherein the distance of occurrence is inherently defined as n x λ/2 (page 3, first paragraph).

Since the specification does not indicate otherwise, the examiner assumes for examination purposes that bactericidal/therapeutic/decreased healing time- effects are intrinsic properties of standing waves/radiation pressure applied to a wound.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 9, 10 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. '499 of record

Martin discloses an ultrasound transducer (805) capable of generating standing waves and capable of being adjusted with respect to distance to an external wound. See fig. 8A and B and col. 10 lines 22-45. Martin further teaches wherein the

ultrasound frequency is 0.5-20MHz and wherein continuous or pulsed energy may be used (col. 9 lines 15-17).

8. Claims 9-11 and 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Duarte '864 of record.

Duarte et al. disclose a surface acoustic wave (SAW) device (14) including a transducer (16) capable of generating standing ultrasound waves (as evidenced by 5,895,362 of record col. 4 lines 39-42; and 5,520,612 of record) and capable of being adjusted with respect to distance to an external wound. Duarte et al. also disclose frequencies between 20 kHz and 10MHz and wherein pulsed or modulated frequencies may be used. Duarte et al. additionally disclose a "bushing" (82).

9. Claims 9-11 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Winder et al. '612 of record

Winder et al. disclose a transducer (10) generating standing ultrasound waves and capable of being adjusted with respect to distance to an external wound. Winder et al. also disclose frequencies up to 10MHz and wherein pulsed or modulated frequencies may be used. Winder et al. additionally disclose a "bushing" (33).

Response to Arguments

10. Applicant's arguments filed 06/29/2004 have been fully considered but they are not persuasive. In response to applicant's argument that Martin et al. does not disclose a system for treating an external wound and a means for creating and maintaining ultrasound standing waves in air, a recitation of the intended use of the claimed invention must result in a *structural difference* between the claimed invention and the

prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's interim supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shawna J. Shaw
Primary Examiner
Art Unit: 3737